K030944

JUN 20 2003

510(k) Summary

Submitter:	Edwards Lifesciences LLC One Edwards Way Irvine, California 92614 USA
Contact:	Jason Smith, Senior Regulatory Affairs Specialist Phone: 949-250-2662 Fax: 949-250-3579
Date prepared:	March 25, 2003
Trade Name:	Edwards Lifesciences Percutaneous Sheath Introducers with Oligon™ material
Common Name:	Catheter Introducer (21 CFR 870.1340)
Predicate Devices:	Edwards Lifesciences Percutaneous Sheath Introducers with Oligon™ material Surgical Specialities' Sharpoint DC-0218 Suture
Device Description:	The Edwards Lifesciences Percutaneous Sheath Introducers with Oligon™ material are used to access the venous system and to facilitate catheter insertion. Edwards Lifesciences wishes to package the Edwards Lifesciences Percutaneous Sheath Introducers with Oligon™ material in a convenience kit. One of the components of the kit is a silk suture. The suture manufacturer provides the suture either gamma sterilized or non-sterile. Edwards wishes to receive the suture non-sterile, with ethylene oxide sterilization as the final sterilization process for the kit, including the suture. The reason for this submission is the change in sterilization process for the suture component of the kit.
Indications for Use:	The Edwards Lifesciences Percutaneous Sheath Introducers with Oligon™ material are indicated for use in patients requiring access of the venous system and to facilitate catheter insertion (e.g. pulmonary artery or infusion catheter).
Comparative Analysis:	The introducer is identical to the predicate Edwards Lifesciences Percutaneous Sheath Introducer with Oligon™ material. The ethylene oxide-sterilized sutures

	have been demonstrated to be in compliance with USP 25, Nonabsorbable Surgical Sutures.
Functional/Safety Testing:	The ethylene-oxide sterilized sutures have successfully undergone functional and biocompatibility testing. They have been shown to be in compliance with USP 25, Nonabsorbable Surgical Sutures.
Conclusion:	The Edwards Lifesciences Percutaneous Sheath Introducers with Oligon™ material are substantially equivalent to the predicate devices. The ethylene-oxide sterilized sutures used in the The Edwards Lifesciences Percutaneous Sheath Introducers with Oligon™ material are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 20 2003

Edwards Lifesciences LLC
c/o Mr. Jason Smith
One Edwards Way
Irvine, CA 92614

Re: K030944
Percutaneous Sheath Introducers with Oligon™ Material
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: March 25, 2003
Received: March 26, 2003

Dear Mr. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Bram Zuckerman,
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K030944

Device Name: Edwards Lifesciences Percutaneous Sheath Introducers with Oligon™ material

Indications For Use:

The Edwards Lifesciences Percutaneous Sheath Introducers with Oligon™ material are indicated for use in patients requiring access of the venous system and to facilitate catheter insertion (e.g. pulmonary artery or infusion catheter).

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number

Prescription Use X OR Over-The-Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)